



(43) International Publication Date
12 May 2005 (12.05.2005)

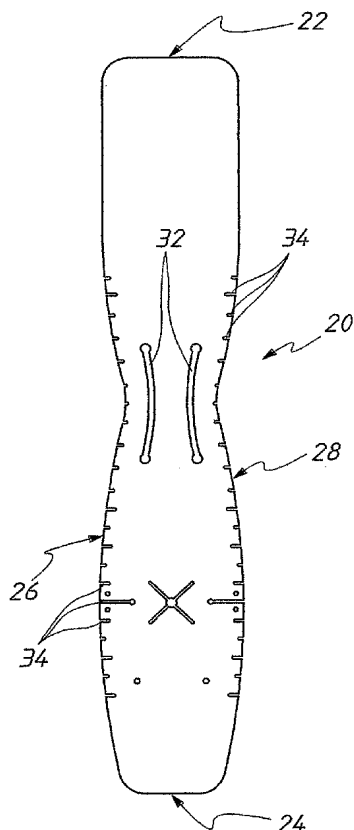
PCT

(10) International Publication Number
WO 2005/041783 A1

- | | |
|---|--|
| <p>(51) International Patent Classification⁷: A61B 17/12</p> <p>(21) International Application Number:
PCT/AU2004/001484</p> <p>(22) International Filing Date: 28 October 2004 (28.10.2004)</p> <p>(25) Filing Language: English</p> <p>(26) Publication Language: English</p> <p>(30) Priority Data:
2003905992 30 October 2003 (30.10.2003) AU</p> <p>(71) Applicant (for all designated States except US): SUNSHINE HEART COMPANY PTY LTD [AU/AU]; 2A River Street, Birchgrove, NSW 2041 (AU).</p> <p>(72) Inventors; and</p> <p>(75) Inventors/Applicants (for US only): MILLER, Scott, Hugh [AU/AU]; 35/10 Darley Road, Manly, NSW 2095</p> | <p>(AU). PETERS, William, Suttle [NZ/NZ]; 93 Bassett Road, Remuera, Auckland 1005 (NZ). DE PLATER, Gemma [AU/AU]; 2/135 Brooke Street, Coogee, NSW 2034 (AU).</p> <p>(74) Agent: SPRUSON & FERGUSON; GPO Box 3898, Sydney, NSW 2001 (AU).</p> <p>(81) Designated States (<i>unless otherwise indicated, for every kind of national protection available</i>): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.</p> <p>(84) Designated States (<i>unless otherwise indicated, for every kind of regional protection available</i>): ARIPO (BW, GH,</p> |
|---|--|

[Continued on next page]

(54) Title: A WRAP



(57) Abstract: A wrap (20) for securing about a blood vessel (36) by encasing a section of the vessel. The wrap (20) being of thin flexible construction having two ends (22, 24) and two sides (26, 28). The wrap (20) is more elastic or stretchable at, near, or along at least some of its sides (22, 24) compared to at, near, or along its centre, to provide strain relief from wrapped to unwrapped aorta. The wrap (20) is not inelastic, so that loss of aortic compliance is minimised or enhanced. The wrap (20) is adapted to apply, in use, less compressive force at, near, or along at least some of its sides (22, 24) compared to at, near, or along its centre.



GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

A WRAP

Field of the Invention

The present invention relates to a wrap for securing about a blood vessel, and in particular for holding a vessel deformer adjacent an arterial vessel.

5 The invention has been primarily developed for use in securing the inflatable balloon or chamber of an implantable counter-pulsation heart assist device against the ascending aorta and will be described hereinafter with reference to this application.

Background of the Invention

10 The Applicant's International PCT Patent Application Nos. PCT/AU00/00654 and PCT/AU01/01187 disclose heart assist devices, systems and methods. More particularly, these specifications disclose vessel deformers in the form of inflatable balloon or chambers which form part of implantable counter-pulsation heart assist devices. The balloon or chambers are cyclically inflated and deflated and used to compress the patient's ascending aorta during diastole and release the compression during
15 systole.

 The balloon or chamber are generally secured to the aorta by a substantially non-elastic wrap or sheath, which is secured around a section of the aorta with the balloon or chamber therebetween. For the heart assist device to function efficiently, it is necessary that the wrap be a snug fit around the aorta when the balloon or chamber is deflated.

20 Hitherto, wraps have been manufactured from a length of substantially inflexible woven polyester material. The disadvantage of known wraps will be described with reference to Fig. 3 which shows a section of aorta 10 encased by a known wrap 12. If the wrap 12 is over-tightened (as shown), its sides cause a sharp depression or kink in the aorta 10, in the regions indicated by the reference numeral 14. This can also occur due to
25 the aorta 10 enlarging slightly as the patient recovers or with age. This depression/kinking places a higher strain on the wall of the aorta 10 and can damage same. Also, the kink in the internal wall of the aorta 10 induces turbulence in the blood flow, which increases the likelihood of plaque formation.

 Wrapping a curved vessel with a flat straight piece of fabric also leads to
30 bunching or folding of the fabric. This is undesirable as it encourages secondary growth or potential infection in the bunched/folded region and results in uneven load distribution.

It is also known to place static wraps around blood vessels, for instance to reinforce vessels suffering from aneurysmal disease.

Any aortic compliance may be lost by placement of non-elastic or non shape-changing wrap, which may reduce the natural advantage of aortic compliance on cardiac function.

It is an object of the present invention to provide a wrap that substantially overcome or at least ameliorate one or more of the above disadvantages.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides a wrap for securing about a blood vessel by encasing a section of the vessel, the wrap being of thin flexible construction having two ends and two sides. It is preferable that the wrap is more elastic or stretchable at, near, or along at least some of its sides compared to at, near, or along its centre, to provide strain relief from wrapped to unwrapped aorta.

It is preferable that the wrap is not inelastic, and that loss of aortic compliance is minimised, or in fact enhanced.

In a second aspect, the present invention provides a wrap for securing about a blood vessel by encasing a section of the vessel, the wrap being of thin flexible construction having two ends and two sides and being adapted to apply, in use, less compressive force at, near, or along at least some of its sides compared to at, near, or along its centre.

The wrap is preferably adapted for securing a vessel deformer adjacent the vessel, by sandwiching the deformer between the vessel and the wrap. The vessel deformer is preferably part of an implantable counter-pulsation heart assist device and most preferably is in the form of an inflatable balloon or chamber. The wrap is preferably adapted to secure the inflatable balloon or chamber against an aorta, most preferably the ascending aorta.

The wrap is preferably of woven or knitted construction, or a combination, and made of material such as polyester or PET (polyethylene terephthalate).

In one form, the wrap has slits along some of its sides, most preferably a series of spaced part slits that are normal to the direction of the sides. The slits make those parts of the sides more elastic or stretchable than the centre of the wrap.

In another form, the wrap has warp fibres at, near, or along its sides that are more elastic than the warp fibres at, near, or along its centre. In this form, the warp fibres, near

or along its sides are preferably crimped and the warp fibres at, near, or along its centre are preferably un-crimped or less crimped.

In another form, the wrap includes a strip of substantially centrally placed material, that has a tensile strength greater than that of the rest of the wrap.

5 In another form, the woven fabric may be cut on the bias to allow a more conformal wrap and with some improved elasticity along the edge areas of the wrap.

The two sides of the wrap can be of similar, or differing, elasticity or stretchability to each other. In the case of differing, the more elastic or stretchable side is positioned closer to the heart, as this is where there is greater movement.

10 In a yet further form, the wrap is thinner at, near, or along its sides compared to at, near, or along its centre.

The wrap is preferably about six times longer than it is wide, most preferably with a slimmed region at or near its longitudinal midpoint. The wrap desirably includes one or more, preferably two, longitudinal slits near its thinned region to allow the wrap to
15 conform radially more closely with the inner curve of the aorta. The wrap is preferably shaped to allow good conformance with the curved aorta – the slits allow improved conformity. The wrap preferably also includes an opening for a fluid tube.

In another embodiment, the wrap may be coated with a material to reduce its surface area and to limit tissue ingrowth. The wrap is preferably coated on one or both
20 sides with either silicone or polyurethane or a co-polymer of both.

In another embodiment the wrap may be of an open weave structure (such as by gauze weaving using a leno weave) or a mesh, to allow vascular ingrowth from external to the wrap to provide nourishment of the outer wall of the aorta. The slits on the inner curvature of the wrap may also achieve this, as may further slits circumferentially on the
25 lateral or outer curvature aspects of the wrap.

Brief Description of the Drawings

Preferred embodiments of the present invention will now be described, by way of examples only, with reference to the accompanying drawings in which:

Fig. 1 is a top view of a first embodiment of a wrap according to the invention;

30 Fig. 2 is a perspective view of the wrap shown in Fig. 1;

Fig. 3 is a schematic cross-sectional view of a prior art wrap around an aorta;

Fig. 4 is a schematic cross-sectional view of the wrap shown in Fig. 1 around an aorta;

Fig. 5 is a partial top view of a second embodiment of a wrap according to the invention; and

Fig. 6 is a partial top view of a third embodiment according to the invention.

Detailed Description of the Preferred Embodiment

5 Referring firstly to Fig. 1 and 2, there is shown a wrap 20 according to a first embodiment of the invention. The wrap 20 is produced from woven polyester or similar non-absorbable biostable and biocompatible material and includes ends 22, 24 and sides 26, 28.

The wrap 20 includes an opening 30 for a fluid tube to be connected to, for
10 example, the inflatable balloon or chamber (not shown) of a heart assist device. The wrap 20 also includes a thinned region with a pair of curved longitudinal slits 32, which serve to prevent the wrap from kinking or folding when it is wrapped around a curved portion of aorta.

About two-thirds of the sides 26, 28 of the wrap 20 include a series of spaced
15 apart slits 34 which are substantially normal to the longitudinal axis of the wrap 20. These slits 34 results in those parts of the sides 26, 28 of the wrap 20 being more elastic or stretchable than the intermediate central portion of the wrap 20. As a result, when the wrap 20 is placed around a section of aorta and tightened to a snug fit, less tension is placed in the sides 26, 28 or edges of the wrap 20 than in the centre. This avoids the
20 depression/kinking, and associated high strain levels, associated with known wraps (as was discussed in relation to Fig. 3).

A schematic illustration of the wrap 20 around a section of aorta 36 is shown in Fig. 4. The regions 38 of the aorta 36 adjacent the sides 26, 28 of the wrap have a smooth curved transition from a larger to smaller diameter. These curved transition regions 38
25 result in less strain in the wall of the aorta 36, which reduces the chance of damage to same. The curved transition zones 38 also reduce turbulence in the blood flow through the aorta 36 and thereby reduce the likelihood of plaque formation.

A second embodiment of wrap 40 is shown in Fig. 5. In this embodiment, the wrap 40 according to the invention is again of woven polyester construction with
30 longitudinal warp fibres 42 and lateral weft fibres 44. In the wrap 40, the warp fibres 46 adjacent the sides of the wrap 40 are made crimped which makes them more elastic or stretchable than the un-crimped warp fibres 48 in the centre of the wrap 40.

Fig. 6 shows another embodiment of wrap 50 according to the invention which is again of woven polyester construction. The wrap 50 includes a second polyester strip 52

- 5 -

attached to its centre. The strip 52 has a tensile strength greater than that of the rest of the wrap 50 which results in the sides 54, 56 being more elastic or stretchable than the centre 52.

5 It will be appreciated by persons skilled in the art that numerous variations and/or modifications can be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly defined.

CLAIMS:

1. A wrap for securing about a blood vessel by encasing a section of the vessel, the wrap being of thin flexible construction having two ends and two sides, wherein the wrap is more elastic or stretchable at, near, or along at least some of its sides
5 compared to at, near, or along its centre, to provide strain relief from wrapped to unwrapped aorta.
2. The wrap as claimed in claim 1, wherein the wrap is not inelastic, whereby loss of aortic compliance is minimised, or enhanced.
3. A wrap for securing about a blood vessel by encasing a section of the
10 vessel, the wrap being of thin flexible construction having two ends and two sides and being adapted to apply, in use, less compressive force at, near, or along at least some of its sides compared to at, near, or along its centre.
4. The wrap as claimed in claim 1, 2 or 3, wherein the wrap is adapted for securing a vessel deformer adjacent the vessel, by sandwiching the deformer between the
15 vessel and the wrap.
5. The wrap as claimed in claim 4, wherein the vessel deformer is part of an implantable counter-pulsation heart assist device.
6. The wrap as claimed in claim 5, wherein the vessel deformer is an inflatable balloon or chamber.
- 20 7. The wrap as claimed in claim 6, wherein the wrap is adapted to secure the inflatable balloon or chamber against an aorta.
8. The wrap as claimed in claim 7, wherein the wrap is adapted to secure the inflatable balloon or chamber against an ascending aorta.
9. The wrap as claimed in any one of the preceding claims, wherein the
25 wrap is of woven or knitted construction, or a combination of those constructions.
10. The wrap as claimed in claim 9, wherein the wrap is made of polyester or PET (polyethylene terephthalate).
11. The wrap as claimed in any one of the preceding claims, wherein the wrap has slits along some of its sides.
- 30 12. The wrap as claimed in claim 11, wherein the wrap has a series of spaced part slits that are normal to the direction of the sides.
13. The wrap as claimed in any one of claims 1 to 10, wherein the wrap has warp fibres at, near, or along its sides that are more elastic than the warp fibres at, near, or along its centre.

14. The wrap as claimed in claim 13, wherein the warp fibres, near or along its sides are crimped and the warp fibres at, near, or along its centre are un-crimped or less crimped.

15. The wrap as claimed in any one of claims 1 to 10, wherein the wrap
5 includes a strip of substantially centrally placed material, the strip having a tensile strength greater than that of the rest of the wrap.

16. The wrap as claimed in claim 15, wherein the two sides of the wrap can be of similar, or differing, elasticity or stretchability to each other.

17. The wrap as claimed in any of claims 1 to 10, wherein the wrap is made
10 from woven fabric cut on the bias and is more elastic at or near its sides.

18. The wrap as claimed in any one of the preceding claims, wherein the wrap is thinner at, near, or along its sides compared to at, near, or along its centre.

19. The wrap as claimed in any one of the preceding claims, wherein the wrap is about six times longer than it is wide.

20. The wrap as claimed in any one of the preceding claims, wherein the
15 wrap has a slimmed region at or near its longitudinal midpoint.

21. The wrap as claimed in claim 20, wherein the wrap includes one or more longitudinal slits near its thinned region to allow the wrap to conform radially more closely with the inner curve of the aorta.

22. The wrap as claimed in any one of any one of the preceding claims,
20 wherein the wrap is shaped to allow good conformance with the curved aorta.

23. The wrap as claimed in any one of the preceding claims, wherein the wrap also includes an opening for a fluid tube.

24. The wrap as claimed in any one of the preceding claims, wherein the
25 wrap is coated with a material to reduce its surface area and to limit tissue ingrowth.

25. The wrap as claimed in claim 24, wherein the wrap is coated on one or both sides with either silicone or polyurethane or a co-polymer of both silicone and polyurethane.

26. The wrap as claimed in any one of claims 1 to 22, wherein the wrap has
30 an open weave or mesh structure.

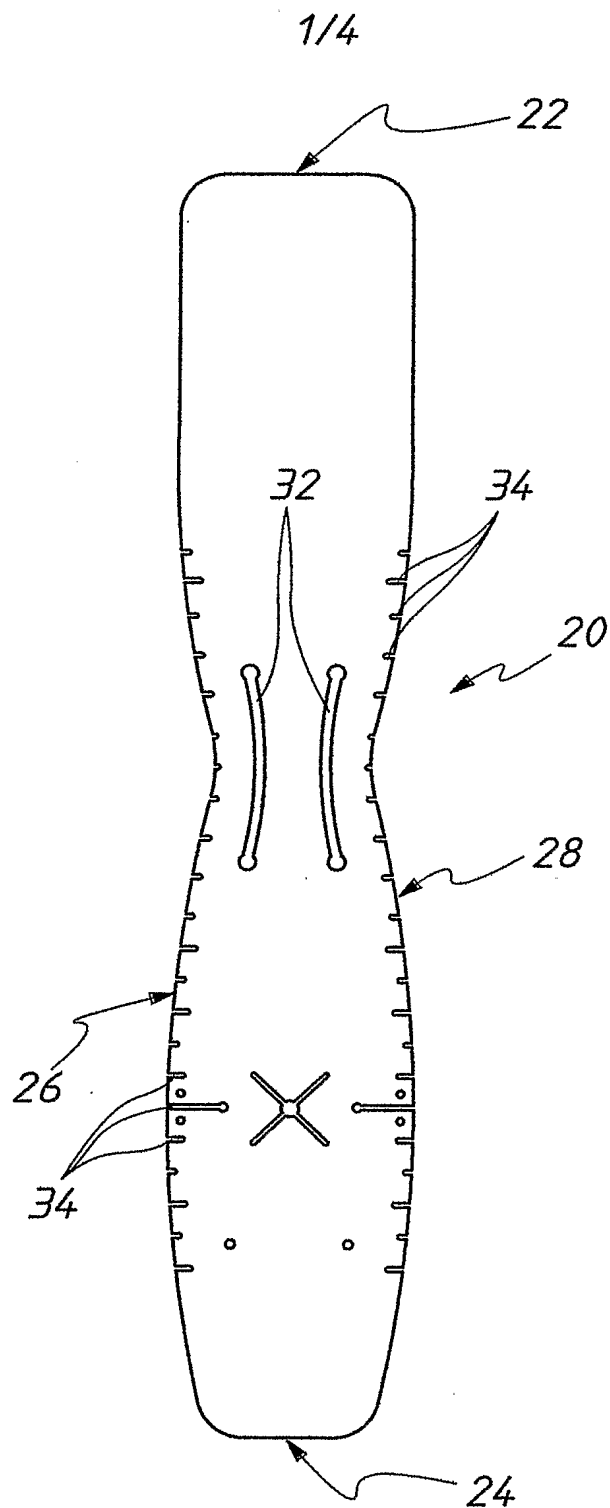


FIG. 1

2/4

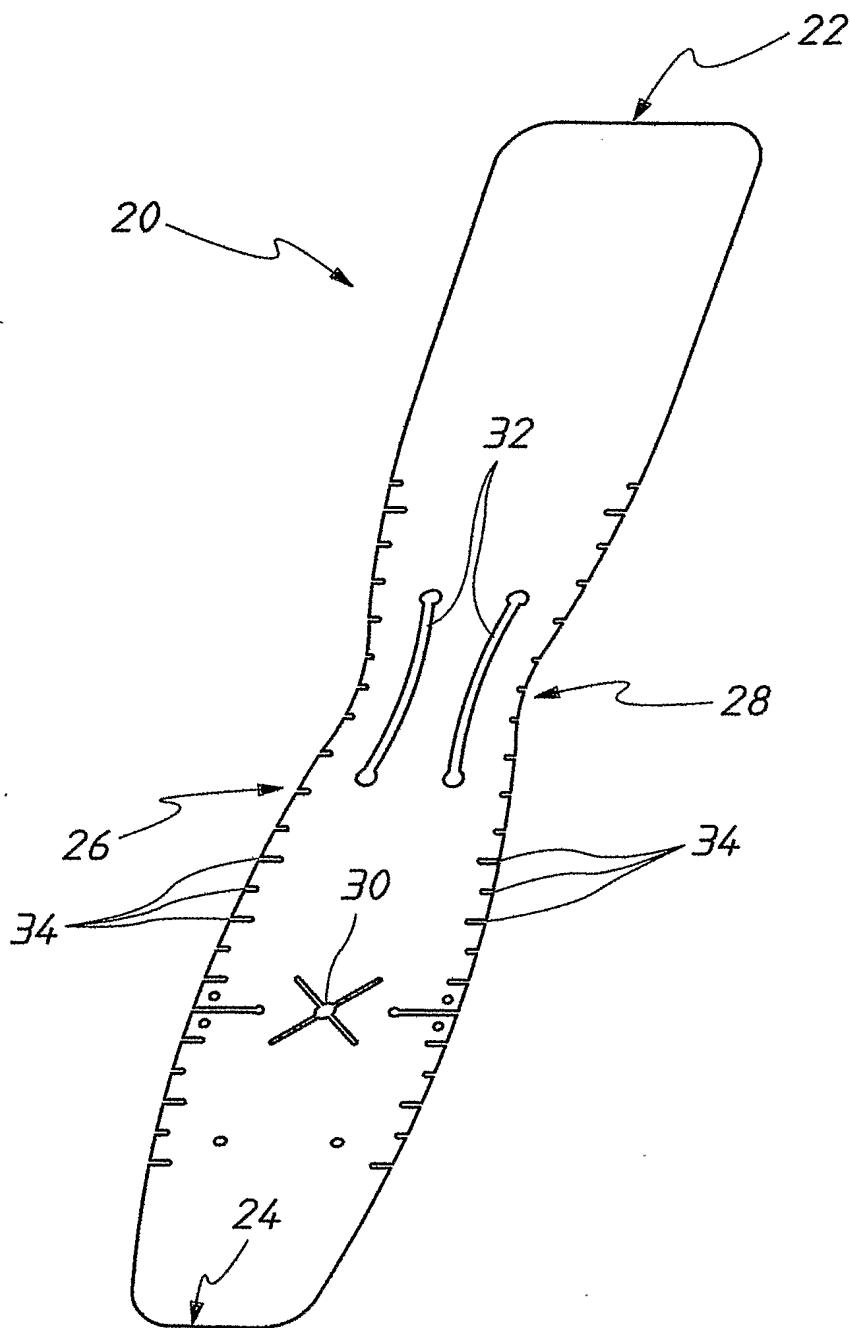


FIG. 2

3/4

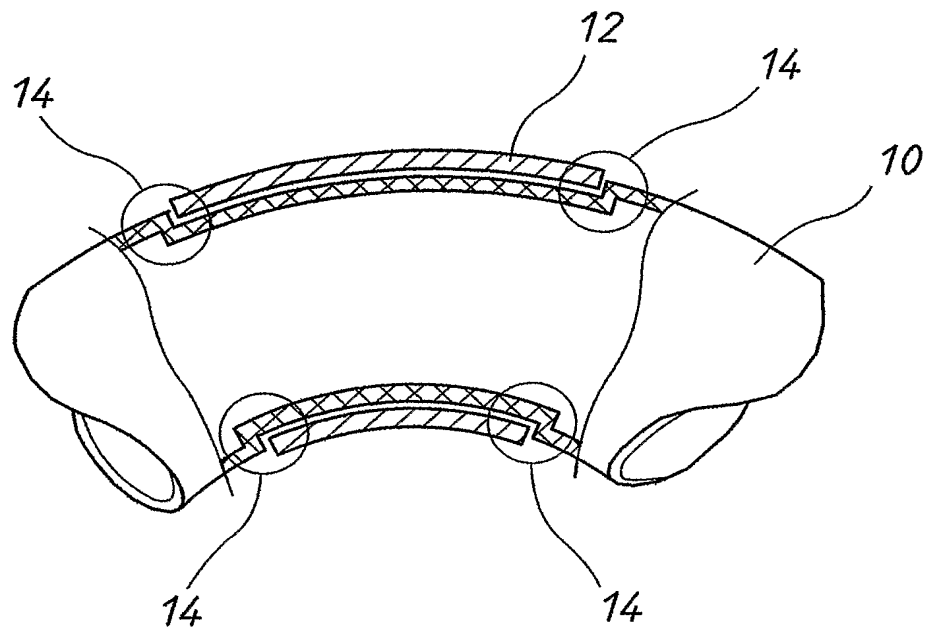


FIG. 3

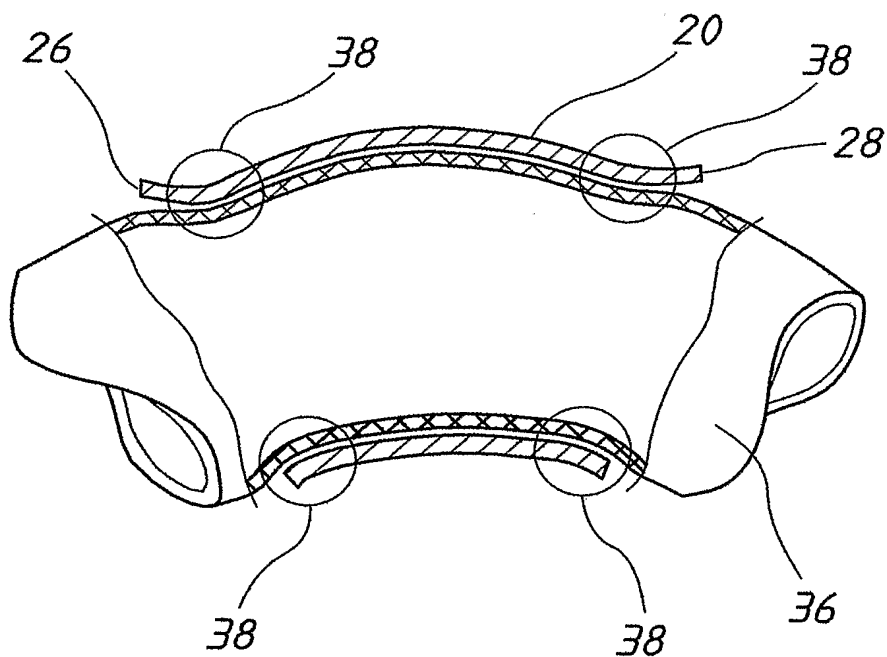


FIG. 4

4/4

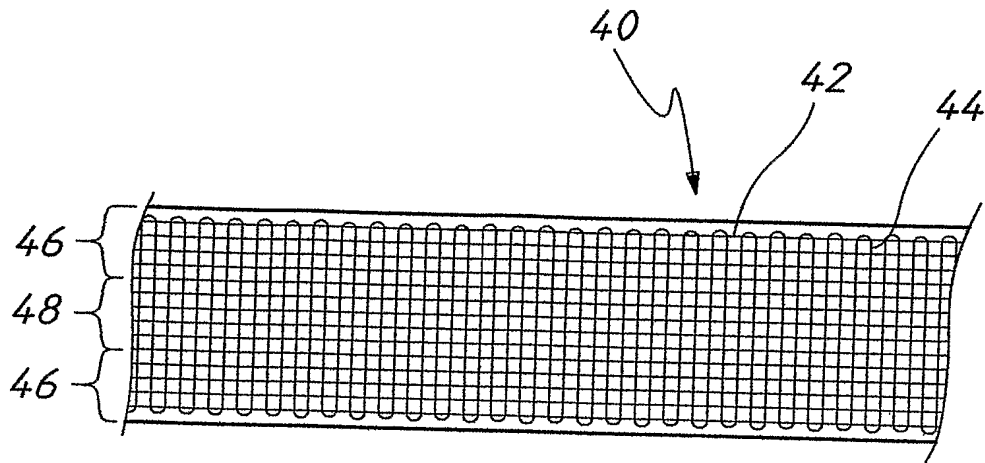


FIG. 5

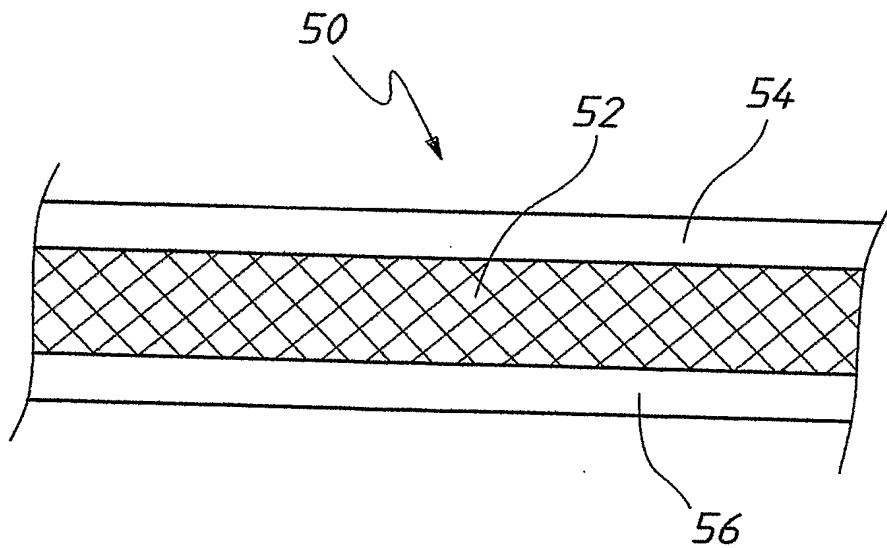


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/001484

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. ⁷ : A61B 17/12 According to International Patent Classification (IPC) or to both national classification and IPC					
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI IPC A61B/- A61F/-A61M/- + keywords: (aorta vascul wrap encase envelop surround elastic stretch and similar terms)					
C. DOCUMENTS CONSIDERED TO BE RELEVANT					
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.			
A	WO 1995005122 A1 (MIND-E.M.S.G. LTD) 23 February 1995 Whole document				
<div style="display: flex; justify-content: space-between; align-items: center;"> <input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex </div>					
<table style="width: 100%; border: none;"> <tr> <td style="width: 33%; vertical-align: top;"> <p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </td> <td style="width: 33%; vertical-align: top;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> </td> <td style="width: 33%;"></td> </tr> </table>			<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>	
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p>	<p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>				
Date of the actual completion of the international search 23 November 2004		Date of mailing of the international search report <div style="text-align: right;">29 NOV 2004</div>			
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustrialia.gov.au Facsimile No. (02) 6285 3929		Authorized officer Sue Thomas Telephone No : (02) 6283 2454			

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2004/001484

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	1995005122	AU	74999/94	IL	106738	US	5476471

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

CORRECTED VERSION

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
12 May 2005 (12.05.2005)

PCT

(10) International Publication Number
WO 2005/041783 A1

(51) International Patent Classification⁷: **A61B 17/12**

(21) International Application Number:
PCT/AU2004/001484

(22) International Filing Date: 28 October 2004 (28.10.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2003905992 30 October 2003 (30.10.2003) AU

(71) Applicant (for all designated States except US): **SUNSHINE HEART COMPANY PTY LTD** [AU/AU]; 2A River Street, Birchgrove, NSW 2041 (AU).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **MILLER, Scott,**

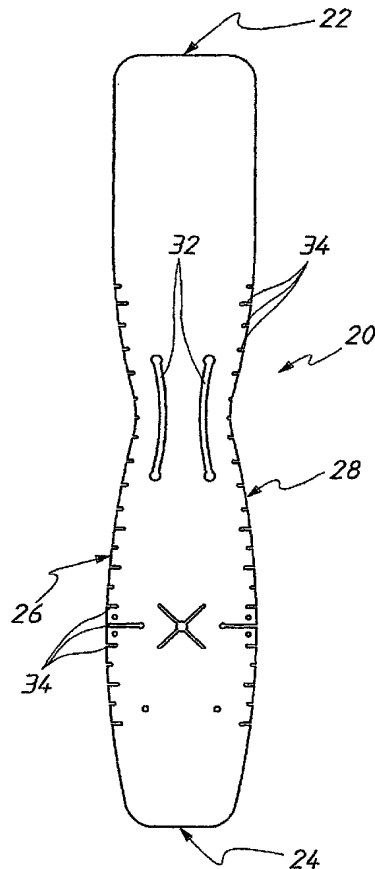
Hugh [US/AU]; 35/10 Darley Road, Manly, NSW 2095 (AU). **PETERS, William, Suttle** [NZ/NZ]; 93 Bassett Road, Remuera, Auckland 1005 (NZ). **DE PLATER, Gemma** [AU/AU]; 2/135 Brooke Street, Coogee, NSW 2034 (AU).

(74) Agent: **SPRUSON & FERGUSON**; GPO Box 3898, Sydney, NSW 2001 (AU).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,

[Continued on next page]

(54) Title: A WRAP



(57) Abstract: A wrap (20) for securing about a blood vessel (36) by encasing a section of the vessel. The wrap (20) being of thin flexible construction having two ends (22, 24) and two sides (26, 28). The wrap (20) is more elastic or stretchable at, near, or along at least some of its sides (22, 24) compared to at, near, or along its centre, to provide strain relief from wrapped to unwrapped aorta. The wrap (20) is not inelastic, so that loss of aortic compliance is minimised or enhanced. The wrap (20) is adapted to apply, in use, less compressive force at, near, or along at least some of its sides (22, 24) compared to at, near, or along its centre.

WO 2005/041783 A1



TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— with international search report

(48) Date of publication of this corrected version:

21 July 2005

(15) Information about Correction:

see PCT Gazette No. 29/2005 of 21 July 2005, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.